REMARKS

In the specification, the paragraph beginning on page 12, line 20 has been amended to correct a minor typographic error. No new matter has been added.

Claims 18, 21, 36 and 37 were presented for examination. Claims 18, 21, 36 and 37 were rejected. Claims 21 and 36 have been amended. Support for these amendments may be found on page 3, lines 25-30; page 10, line 32 through page 12, line 33; page 16, lines 3-6; page 17, lines 25-29; page 18, lines 1-3 and lines 17-23. No new matter has been added

Statement of the Substance of the Interview

On March 14, 2008 and April 10, 2008, Kristina E. Swanson, on behalf of the Applicant, conducted telephone interviews with Examiner Deborah Leslie Malamud. In the Office Action of January 22, 2008, all claims were rejected. Ms. Swanson and the Examiner discussed suggested amendments to claims 21 and 36 to help distinguish the claimed invention from the cited prior art. The Examiner agreed that the claims as amended did overcome the cited prior art (i.e., the cited prior art does not recite a transseptal needle). The Examiner further suggested amending the claims to positively distinguish the structural differences of the unipolar and bipolar electrodes and the location signal generator from the prior art.

Rejections Under 35 U.S.C. § 102(b)

Claims 21 and 36 were rejected under 35 U.S.C. § 102(b) as being anticipated by Svenson et al. Applicant respectfully traverses.

Claim 21 recites a transseptal apparatus for locating the fossa ovalis in a patient and performing a transseptal puncture of the fossa ovalis. The apparatus comprises a hollow sheath having a distal end, a transseptal needle and a catheter for use in transseptal punctures. The

catheter comprises a hollow lumen and only two electrodes. A first electrode positioned at the distal end of the catheter and a second electrode positioned on the catheter and spaced proximally from the first electrode. The first and the second electrode are sensors of electrophysical activity of an interartial septum. The catheter is configured to be inserted into the hollow sheath for transseptal puncture and to receive the transseptal needle urged through the lumen until a tip of the needle protrudes beyond the distal end of the catheter. The catheter removably contacts the hollow sheath. The catheter is also configured such that the distal end of the catheter serves as both an electrophysiology mapping catheter for locating the fossa ovalis and a dilator suitable for penetrating the fossa ovalis during a transseptal puncture procedure by urging the catheter over the transseptal needle positioned within the lumen of the catheter. Lastly, the apparatus comprises a recording device for the generation and recording of unipolar and bipolar electrograms. The recording device in electrical communication with the electrodes of the catheter. The recording device generates the unipolar electrograms from the electrophysical activity sensed by the first electrode and the bipolar electrograms from the electrophysical activity sensed by both the first electrode and the second electrode.

Svenson recites a process and apparatus for mapping of tachyarrhythmia. However, Svenson fails to disclose a transseptal needle and the generation of the unipolar electrograms from the electrophysical activity of the interartial septum sensed by the first electrode (positioned at the distal end of the cathether) and the bipolar electrograms from the electrophysical activity of the interartial septum sensed by both the first electrode (positioned at the distal end of the catheter) and the second electrode (positioned proximally from the first electrode along the catheter) (see page 13, lines 13-18; page 14, lines 8-16 and lines 28-33; page 17, lines 14-29 of the Specification and Fig. 6, elements 35 and 36 and Figs. 7 and 8, elements 65 and 66). Instead, Svenson discloses bipolar electrodes on the distal end of the polymer member and a unipolar electrode at a spaced distance from the bipolar electrodes (Abstract; Col. 2, lines 32-35; Col. 4, lines 13-37; Figs 3 and 4, elements 40, 42, and 44). Further, the first and second electrode sensors, in the claimed invention, can act either as two independent unipolar electrodes or as a bipolar electrode pair for sensing electrophysical activity of the interatrial septum (see page 14,

lines 9-18 of the Specification). There is no teaching or motivation to show that the bipolar electrodes at the distal end of a single catheter in Svenson have the capability to be unipolar electrodes. Nor is there any teaching or motivation that the Svenson unipolar electrode and the tip bipolar electrodes can form a bipolar electrode pair. Further, there is no teaching or motivation that the electrodes in Svenson are sensors of electrophyical activity of the interatrial spetum

Additionally, there is no teaching or motivation that Svenson's catheter could be used to perform a transseptal puncture of the fossa ovalis in the interatrial septum using a transseptal needle and a catheter/dilator as disclosed in the claimed invention. In contrast, the catheter in Svenson teaches accommodating an ablation catheter to ablate arrhythmogenic sites in the ventricle (Abstract). A transseptal needle and an ablation device are two different devices and the atrium and the ventricle are different chambers of the heart. Further, Svenson "requires a hole in the heart" for insertion of the catheter (Col. 3, lines 23-25), whereas the claimed invention the catheter is inserted into the femoral vein and advanced into the superior vena cava to position the distal end of the catheter against the interatrial septum. Therefore, Applicant believes that claim 21 is not anticipated by Svenson and request the withdrawal of the rejection to claim 21.

Claim 36 recites a transseptal apparatus for locating the fossa ovalis in a patient and performing a transseptal puncture of the fossa ovalis. The apparatus comprises a hollow sheath having a distal end, a transseptal needle and a catheter for use in transseptal punctures. The catheter comprises a hollow lumen and only two electrodes. A first electrode positioned at the distal end of the catheter and a second electrode positioned on the catheter and spaced proximally from the first electrode. The catheter is configured to be inserted into the hollow sheath for transseptal puncture and to receive the transseptal needle urged through the lumen until a tip of the needle protrudes beyond the distal end of the catheter and wherein the catheter removably contacts the hollow sheath. The catheter is configured such that the distal end of the catheter serves as both an electrophysiology mapping catheter for locating the fossa ovalis and a dilator suitable for penetrating the fossa ovalis during a transseptal puncture procedure by urging the

catheter over the transseptal needle positioned within the lumen of the catheter. The catheter is configured such that the transseptal needle may be urged through the lumen tip of the needle protrudes beyond the distal end of the catheter. The apparatus further comprises a location signal generator for providing a location signal to at least one of the electrodes in order to locate the fossa ovalis and a recording device for the generation and recording of electrograms, the recording device in electrical communication with the electrodes. The transseptal apparatus is configured such that a user may identify the fossa ovalis of patient on the basis of at least one of the following parameters: unipolar voltage reduction; signal fractionation; broadened signal; reduced signal slew rate; reduced local myocardial impedance; increased phase angle; and increased pacing threshold.

As discussed above, Svenson recites a process and apparatus for mapping of tachyarrhythmia. Since claim 36 also discloses a transseptal needle as called for in claim 21, Applicant believes that claim 36 is also not anticipated by Svenson and request the withdrawal of the rejection to claim 36.

Additionally, Svenson fails to disclose a location signal generator for providing a location signal to at least one of the electrodes in order to locate the fossa ovalis (see page 10, line 32 through page 12, line 33 of the Specification). In contrast, Svenson discloses the electrode connected to a radio frequency generator or a DC current module for ablating the arrhythmogenic sites (Abstract; Col. 3, lines 3-6; Col. 5, lines 1-8). Svenson fails to disclose a generator that can be used to locate the fossa ovalis. Therefore, Applicant believes that claim 36 is not anticipated by Svenson and request the withdrawal of the rejection to claim 36.

Rejections Under 35 U.S.C. § 103(a)

Claims 18 and 37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Svenson et al. Applicant respectfully traverses.

Claims 18 and 37 depend from the independent claims 21 and 36. These dependent claims are patentable for the same reasons as presented above with respect to the claims from

which they depend. Therefore, Applicant asserts that claims 18 and 37 are also patentable over the prior art and requests withdrawal of the rejection thereof.

Conclusion

For the above reasons, the Applicant respectfully submits that the above claims represent allowable subject matter. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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